

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

ZEAVISION, LLC,)	
)	
Plaintiff,)	
)	Case No. 4:21-cv-01487-HEA
v.)	
)	JURY TRIAL DEMANDED
BAUSCH & LOMB INCORPORATED,)	
)	
Defendant.)	

PLAINTIFF'S FIRST AMENDED COMPLAINT

Plaintiff ZeaVision, LLC ("ZeaVision") states as follows for its First Amended Complaint against Defendants Bausch & Lomb Incorporated ("Bausch & Lomb"):

PARTIES, JURISDICTION AND VENUE

1. ZeaVision is a Delaware limited liability company with a principal place of business at 716-I Crown Industrial Court, Chesterfield, Missouri 63005.

2. Upon information and belief, Bausch & Lomb is a New Jersey corporation with at least three regular and established places of business in Missouri located in this judicial district. On information and belief, Bausch & Lomb transacts business within the State of Missouri, within the meaning of 15 U.S.C. § 22, and has a registered agent in Missouri. Bausch & Lomb sells products in the State of Missouri and provides support for products sold to the residents of the State of Missouri. Individuals in Missouri can contact Bausch & Lomb through its website. Further, Bausch & Lomb has filed a lawsuit against ZeaVision and sought *inter partes* review of ZeaVision's patents. These actions all have a substantial effect on ZeaVision, which has its principal place of business in Missouri. In addition, the action of filing a sham lawsuit against ZeaVision is one of the antitrust violations complained of herein.

3. ZeaVision's claims arise under the antitrust and unfair competition laws of the United States, 15 U.S.C. § 1 *et seq.* Subject matter jurisdiction exists pursuant to 28 U.S.C. §§ 1331 and 1337.

4. This Court has personal jurisdiction over Bausch & Lomb. Upon information and belief, Bausch & Lomb owns, uses, or possesses physical places of business in this judicial district located at 499 Sovereign Court, Ballwin, Missouri 63011, 3845 Corporate Centre Drive, O'Fallon, Missouri 63368 and 3365 Tree Court Boulevard, St. Louis, Missouri 63122. Bausch & Lomb is registered to do business in the state of Missouri and with the Missouri Secretary of State under charter No. F00010319. Bausch & Lomb sells Bausch & Lomb products in Missouri that are the subject of this litigation.

5. Bausch & Lomb has also directed monopolistic acts complained of herein to Missouri, including but not limited to filing a frivolous lawsuit against a Missouri corporation. ZeaVision's claims arise out of or relate to Defendants' activities directed to the state of Missouri.

6. Defendants' patent claims and their complaint in the Western District of New York against ZeaVision (the "WDNY Action Against ZeaVision"; C.A. No. 20-CV-6452) are intentionally directed at ZeaVision, a Missouri resident, and are intended to affect the sale of ZeaVision's products in Missouri as well as the ongoing business operations of ZeaVision. Defendants were aware, when they filed the WDNY Action Against ZeaVision, that ZeaVision was a Missouri resident.

7. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 because Bausch & Lomb has committed monopolistic acts affecting a company in this judicial district, has at least three regular and established physical places of business in this judicial district located at 3845 Corporate Centre Drive, O'Fallon, Missouri 63368; 499 Sovereign Court, Ballwin, Missouri

63011 (depicted below); and at 3365 Tree Court Boulevard, St. Louis, Missouri 63122 (depicted below), and both Defendants are subject to personal jurisdiction in this district.



Bausch & Lomb, 499 Sovereign Court, Ballwin, Missouri 63011



Bausch & Lomb, 3365 Tree Court Boulevard, St. Louis, Missouri 63122

8. Bausch & Lomb also does business in this judicial district through a permanent and continuous presence here. Upon information and belief, Bausch & Lomb owns real property located in this judicial district, has employees at its facilities in this judicial district, and pays contractors and/or agents in this judicial district. Further, Bausch & Lomb sells and has sold products related to the present suit, including its PreserVision® line of products, in this judicial district.

FACTS COMMON TO ALL COUNTS

ZeaVision

9. ZeaVision is a leading manufacturer and distributor of orally-ingested formulations for treating or preventing eye disease and vision problems and sells its orally-ingested formulations throughout the United States.

The National Eye Institute's AREDS and AREDS-2 Testing

10. The National Institutes of Health ("NIH"), which is part of the U.S. Department of Health & Human Service, is the nation's medical research agency. The NIH has 27 Institutes and

Centers that focus on different aspects of human health. One of those institutes is the National Eye Institute (“NEI”). The NEI sponsored the Age-Related Eye Disease Study (“AREDS”), a clinical trial designed to investigate the history and risk factors of age-related macular degeneration (“AMD”) and cataracts and to evaluate the effects of various nutritional supplements on the progression of AMD.

11. The initial AREDS trial was conducted between about 1992 and 2001 and the results were published in October 2001. Upon information and belief, the formulations for the initial AREDS trial were supplied by Bausch & Lomb.

12. The original AREDS trial was based on a formulation containing:

- a. 500 mg of vitamin C;
- b. 400 international units of vitamin E;
- c. 15 mg of beta-carotene/25,000 IUs of Vitamin A;
- d. 80 mg of the dietary zinc; and
- e. 2 mg of copper as cupric oxide.

13. Copper was included in the formula to prevent copper deficiency anemia, which is associated with high levels of zinc intake, such as 80 mg of zinc.

14. The original AREDS formulation resulted in a reduced risk of AMD progression for those participants with moderate to advanced AMD.

15. A second five-year trial was commenced in 2006 (“AREDS-2”) and was designed to test whether the original AREDS formulation could be improved by the addition of lutein and zeaxanthin, and the removal of beta-carotene. Upon information and belief, the formulations for the AREDS-2 trial were supplied by Bausch & Lomb.

16. The AREDS-2 trial also evaluated whether the high levels of zinc in the original AREDS formulation (80 mg), which had been reported to cause harmful side effects, could be reduced without reducing the purportedly protective effect of zinc.

17. After testing over 4000 participants over several years, the AREDS-2 trial concluded that reducing the zinc in the formulation from 80 mg to 25 mg had no significant effect on AMD progression. According to the NEI's website, "[t]he investigators found no significant changes in the effectiveness of the formulation when they lowered zinc." (<https://www.nei.nih.gov/research/clinical-trials/age-related-eye-disease-studies-aredsAREDS-2/aredsAREDS-2-frequently-asked-questions>). In other words, the AREDS-2 trial showed that the high levels of zinc (80 mg) -- *twice* the amount of the NIH's maximum daily dosage for zinc as described -- provided no benefit over lower levels of zinc (25 mg).

The NIH's Recommendations of Tolerable Levels of Zinc

18. The NIH also has an Office of Dietary Supplements ("ODS"). According to its website, the mission of the ODS at the NIH "is to strengthen knowledge and understanding of dietary supplements by evaluating scientific information, stimulating and supporting research, disseminating research results, and educating the public to foster an enhanced quality of life and health for the U.S. population." (https://ods.od.nih.gov/About/ODS_Overview.aspx)

19. The ODS at the NIH provides fact sheets to furnish data on dietary supplements to healthcare providers. The fact sheets summarize the findings of various tests and research relating to a number of dietary supplements, including zinc. (<https://ods.od.nih.gov/factsheets/Zinc-HealthProfessional/>.)

20. The NIH's zinc fact sheet includes the following information on the "Recommended Dietary Allowances" for zinc:

Table 1: Recommended Dietary Allowances (RDAs) for Zinc [2]

Age	Male	Female	Pregnancy	Lactation
0–6 months	2 mg*	2 mg*		
7–12 months	3 mg	3 mg		
1–3 years	3 mg	3 mg		
4–8 years	5 mg	5 mg		
9–13 years	8 mg	8 mg		
14–18 years	11 mg	9 mg	12 mg	13 mg
19+ years	11 mg	8 mg	11 mg	12 mg

* Adequate Intake (AI)

21. In other words, the NIH recommends that adults should consume between 8 mg and 13 mg of zinc per day.

22. The NIH’s zinc fact sheet also includes the following information on the maximum tolerable “Upper Intake Levels” for zinc:

Table 3: Tolerable Upper Intake Levels (ULs) for Zinc [2]

Age	Male	Female	Pregnant	Lactating
0–6 months	4 mg	4 mg		
7–12 months	5 mg	5 mg		
1–3 years	7 mg	7 mg		
4–8 years	12 mg	12 mg		
9–13 years	23 mg	23 mg		
14–18 years	34 mg	34 mg	34 mg	34 mg
19+ years	40 mg	40 mg	40 mg	40 mg

23. From this table, the NIH recommends that an adult should consume no more than 40 mg of zinc per day. The NIH’s website further explains the health risks associated with

excessive zinc levels. Citing to a medical journal article, the NIH identifies the health risks specifically associated with the 80 mg of zinc used in the AREDS trials: “the doses of zinc used in the AREDS trial (80 mg per day of zinc in the form of zinc oxide for 6.3 years, on average) have been associated with a *significant increase in hospitalizations for genitourinary causes, raising the possibility that chronically high intakes of zinc adversely affect some aspects of urinary physiology*”. (emphasis added). On information and belief, Bausch & Lomb has knowledge of this specific health risk encountered during the original AREDS trial and other health risks associated with high-zinc levels.

B&L’s Involvement in the AREDS and AREDS-2 Trials and Its Patents

24. As stated on the NEI’s website, Bausch & Lomb provided the formulations that were tested in the AREDS and AREDS-2 trials.

25. Bausch & Lomb is the co-owner of two patents – U.S. Patent Nos. 6,660,297 and 8,603,522 (the “Abused Patents,” for reasons explained *infra*) – which purportedly cover one of the formulations that was the subject of the AREDS-2 trial, although the fact that both patents allegedly have priority dates prior to the occurrence of AREDS-2 calls into question whether there is sufficient support in the specification for such claims.

26. On information and belief, by virtue of NEI researchers also being listed as inventors of the Abused Patents, the United States is a co-owner of the Abused Patents. On information and belief, the United States granted Bausch & Lomb an exclusive license to the United States’ rights in the Abused Patents. Thus, Bausch & Lomb is both a co-owner and an exclusive licensee to the Abused Patents. In other words, Bausch & Lomb is the only entity that can lawfully practice the alleged invention claimed by the Abused Patents, notwithstanding that the AREDS-2 research was funded, at least in part, by federal tax dollars.

27. The claims of the Abused Patents are limited by the high levels of zinc that must be present in the formulation. All of the claims of the Abused Patents require *at least 60 mg* of zinc. Thus, while the AREDS-2 formulation with a high level of zinc (80 mg) may be covered by the Abused Patents, the AREDS-2 formulation with only 25 mg of zinc that was a part of the AREDS-2 trial would *not* be covered by the Abused Patents. As explained above, the NIH recommends that an adult should consume no more than 40 mg of zinc per day and identifies the health risks associated with excessive intake of zinc.

28. Despite there being no apparent clinical benefit to the AREDS-2 formulation having 80 mg of zinc, and despite high levels of zinc being associated with health risks, the NEI's AREDS-2 committee determined that the final formulation to be endorsed by the AREDS-2 trial would include 80 mg of zinc. The NIH explained its conclusion on the lower zinc level as follows:

AREDS-2 found that a formulation providing 25 mg zinc (about one-third the amount in the original formulation) provided the same protective effect against developing advanced AMD. However, because AREDS-2 had fewer participants than the original AREDS study, and fewer than half took the lower zinc formula, the *researchers* view this finding as *preliminary*. They recommend use of an AREDS formulation providing 80 mg zinc

(<https://ods.od.nih.gov/factsheets/Zinc-HealthProfessional/>) (emphasis added)

29. On information and belief, those “researchers” mentioned by the NIH who found the AREDS-2 low-zinc findings to be “preliminary” were made up of professionals at the NEI who worked closely with Bausch & Lomb for years. It is believed that after a reasonable opportunity for further investigation or discovery, it will be revealed that the researchers’ opinions were influenced by their relationship with Bausch & Lomb. As noted on Bausch & Lomb’s website, *both* the original AREDS trial and the AREDS-2 trial were significant, multi-year studies, each with over 4000 participants (4757 participants v. 4203 participants), calling into question the

accuracy of the NEI researchers' characterization of the AREDS-2 low-zinc findings as "preliminary." Further, given that the AREDS-2 trial led to the adoption of zeaxanthin and lutein as being primary constituents of the NEI's final recommendation for an AREDS-2 formula — despite that fact that not all AREDS-2 participants took the zeaxanthin and lutein formula — calls into question how the AREDS-2 lower-zinc results can accurately be dismissed as merely "preliminary," while the AREDS-2 zeaxanthin and lutein results were not.

30. Upon information and belief, Bausch & Lomb, and/or one of its affiliates or subsidiaries, entered into a Cooperative Research and Development Agreement ("CRADA") with NEI, pursuant to which Bausch & Lomb pays an ongoing royalty to NEI and/or certain NEI researchers who are listed as inventors on the Abused Patents.

31. Upon information and belief, some of the NEI researchers who are now listed as co-inventors on Bausch & Lomb's Abused Patents were initially reluctant to be named as a co-inventor and/or refused to execute formal paperwork required by the United States Patent & Trademark Office for the filing of the patent application leading to the Abused Patents.

32. Upon information and belief, the NEI's designation of the AREDS-2 formula with 80 mg of zinc was founded in material part in its monetary interest in sales of Bausch & Lomb PreserVision® products covered by the Abused Patents rather than being guided by the scientific research. It is believed that after a reasonable opportunity for further investigation or discovery additional evidence will support this allegation.

33. Upon information and belief, Bausch & Lomb's close relationship with the NEI, and its involvement with the AREDS-2 trial, allowed Bausch & Lomb to influence the NEI into endorsing the AREDS-2 recommended formula with its higher levels of zinc (80 mg), despite the fact that the AREDS-2 trial showed 25 mg of zinc being equally efficacious and being a *safer*

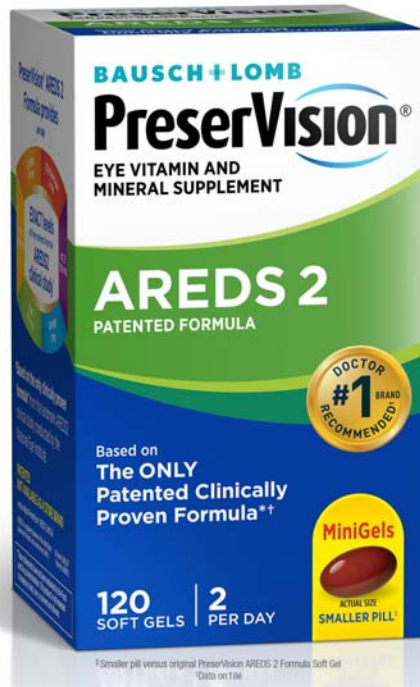
lower level of zinc. Bausch & Lomb's motivation for influencing the NEI to endorse a high-zinc formulation (i.e., the formulation covered by the Abused Patents) was the root of all evil – money. By having the NEI's endorsement of the AREDS-2 formula having higher levels of zinc (instead of *safer* lower levels of zinc), Bausch & Lomb could market and sell its PreserVision® products as being “patented” under the Abused Patents so as to provide Bausch & Lomb with a competitive advantage. With hundreds of millions of dollars in sales of its PreserVision® products having 80 mg of zinc now protected by the Abused Patents, Bausch & Lomb was perfectly content to pay a royalty to the NEI and/or certain NEI researchers who were listed as inventors on the Abused Patents. On the other hand, had the NEI endorsed the AREDS-2 formula having the safer, lower zinc level of 25 mg, that lower-zinc AREDS-2 formula would not been covered by Bausch & Lomb's Abused Patents and Bausch & Lomb would have faced significantly more competition in the marketplace, leading to lower consumer prices.

34. Not surprisingly, Bausch & Lomb proudly markets its “patented” PreserVision® product with the 80 mg of zinc on its website with the NEI endorsement:

The **ONLY** patented eye
vitamin formula backed by
20 years of clinical studies

PreserVision AREDS-2 contains the exact nutrient formula recommended by NEI researchers to help reduce the risk of progression in people with moderate-to-advanced Age-related Macular Degeneration (AMD).

35. Bausch & Lomb also actively markets its PreserVision® product with the 80 mg of zinc as “The ONLY Patented Clinically Proven Formula” on the front face of its product packaging to consumers in the State of Missouri and throughout the United States.



36. Neither the NEI nor Bausch & Lomb have disclosed or publicized that the NEI and/or certain NEI researchers who were responsible for the AREDS-2 trial receive a royalty on the sale of the PreserVision® formula – a formula that contains high levels of zinc despite the research from the AREDS-2 trial showing that lower levels of zinc are equally efficacious and despite it being known that that ingestion of lower levels of zinc reduces other health risks.

37. Bausch & Lomb’s omission here is material because this information was necessary to make the results of the AREDS-2 trial not misleading with respect to its designation of zinc levels.

38. On information belief, Bausch & Lomb also knows that the NIH's tolerable daily upper intake levels for zinc is 40 mg, and the NIH's caution concerning health risks associated with ingestion of higher zinc levels.

39. Upon information and belief, Bausch & Lomb markets its "patented" product as "the exact nutrient formula" recommended by NEI researchers with the intention that consumers will believe that increased zinc levels (80 mg) contribute to the product's efficacy.

40. Bausch & Lomb markets and promotes its "patented" products in the foregoing manner with knowledge that the AREDS-2 trials demonstrated that lower levels of zinc (25 mg) were as clinically beneficial as 80 mg of zinc and that 80 mg of zinc provided no clinical benefit against the progression of AMD.

41. Bausch & Lomb does not disclose in the marketing and sale of its AREDS-2 formula that the NEI and/or certain NEI researchers stood to benefit financially from endorsing a AREDS-2 high-zinc formula in the form of ongoing royalties from Bausch & Lomb on products containing higher-than-necessary levels of zinc. Bausch & Lomb also does not disclose that the levels of zinc contained in its products are potentially harmful.

42. Zinc in high levels for prolonged periods of time is dangerous. In addition to a host of unpleasant side effects including indigestion, diarrhea, headache, nausea, and vomiting, high doses of zinc long term can cause neurological issues including numbness and weakness in the arms and legs, according to the Mayo Clinic. Prolonged exposure at high levels can also adversely affect the immune system and HDL cholesterol ("good" cholesterol). <https://ods.od.nih.gov/factsheets/Zinc-Consumer/>.

43. A study evaluating data obtained in AREDS found that the 80 mg level of zinc ultimately recommended by AREDS correlated with a "significant increase" in genitourinary

ailments, including urinary tract infections. Aaron R. Johnson *et al*, *High Dose Zinc Increases Hospital Admissions Due to Genitourinary Complication*, The Journal of Urology, Feb. 2007, at 639–643.

Bausch & Lomb Weaponizes the Abused Patents

44. Bausch & Lomb has systematically filed meritless patent infringement lawsuits against, on information and belief, substantially all of its competitors that produce oral supplements t of age-related macular degeneration (“AMD”).

45. Bausch & Lomb has filed, on information and belief, sixteen (16) patent infringement lawsuits against numerous, if not all, of its competitors, including ZeaVision, for alleged infringement of two of Bausch and Lomb’s Abused Patents: U.S. Patent No. 8,603,522 (the “’522 Patent”) and U.S. Patent No. 6,660,297 (the “’297 Patent”). The ‘297 Patent expired on March 23, 2021.

46. On information and belief, a number, if not all, of these lawsuits have been meritless. Including the WDNY Action Against ZeaVision. ZeaVision does not infringe Defendants’ patents for a number of reasons. For example, the independent claims of the Abused Patents teach set amounts of zinc:

- a. ‘297 Patent Claims 1, 2, 19, and 20: approximately 4 to 7 times the RDA of zinc¹;
- b. ‘297 Patent Claim 3: not less than approximately 60 mg and not more than 100 mg zinc;
- c. 297 Patent Claim 21: not less than approximately 60 mg and not more than approximately 100 mg zinc;

¹ The ‘297 Patent defines the RDA of zinc as “approximately 15 mg.” ‘297 Patent 6:49.

d. ‘522 Patent Claims 1 and 8: not less than approximately 60 mg and not more than approximately 100 mg zinc;

e. ‘522 Patent Claims 11 and 16: approximately 4 to 7 times the RDA of zinc².

47. Most, if not all, of these lawsuits are objectively baseless and could not reasonably be expected to succeed on the merits.

48. Bausch & Lomb intended to use the petitioning process and accompanying litigation to interfere with its competitors’ businesses, regardless of the petition’s outcome.

49. Bausch & Lomb’s actions represented a series or pattern of sham petitioning. These lawsuits were filed without regard to merit and to use the governmental process to harm market rivals and restrain trade. On information and belief, Bausch & Lomb engaged in the series of sham petitions in subjective bad faith.

50. Only one case located by ZeaVision, *Bausch & Lomb Incorporated et al v. Vitamin Health, Inc.*, Case No. 6:13-cv-06498-JWF (the “Vitamin Health Case”), has reached the claim construction stage. In that case, the court construed “approximately” to mean “reasonably close to.” *Bausch & Lomb Incorporated et al v. Vitamin Health, Inc.*, Case No. 6:13-cv-06498-JWF, Doc. 130 at 13, 14.

51. However, the accused products in a number of the lawsuits for infringement of the Abused Patents filed by Bausch & Lomb do not contain reasonably close to the requisite levels of zinc. And, in some cases, Bausch & Lomb accused the products of meeting the asserted limitations of the Abused Patents in spite of the fact that it plead that the accused products did *not* meet the limitations of the Abused Patents. For example:

² The ‘522 Patent defines the RDA of zinc as “approximately 15 mg.” ‘522 Patent 6:51.

- a. In the Vitamin Health Case, the accused products contained approximately 25 mg of zinc;
- b. ZeaVision's products previously contained approximately 40 mg of zinc and will contain only approximately 25 mg of zinc by February, 2022;
- c. *Bausch & Lomb Inc. et al v. New Era Real Estate Solutions, LLC*, Case No. 1:21-cv-00731-UNA. *See* Doc. 1 ¶ 14 (Bausch & Lomb pleads that accused product contained only 25 mg of zinc, Abused Patents require more as described above).
- d. *Bausch & Lomb Inc. et al v. Macuhealth LP*, Case No. 6:21-cv-06141-CJS. *See* Doc. 1 ¶ 13 (Bausch & Lomb pleads that accused product contained only 25 mg of zinc, Abused Patents require more as described above).
- e. *Bausch & Lomb Inc. et al v. Lunovus LLC*, Case No. 2:20-CV-01766-GMB. On information and belief, the accused product contained approximately 25 mg of zinc.
- f. *Bausch & Lomb Inc. et al v. Advanced Therapeutics, LLC*, Case No. 6:20-cv-06440-CJS. On information and belief, the accused product contained approximately 20 mg of zinc.
- g. *Bausch & Lomb Inc. et al v. Bluebonnet Nutrition Corporation*, Case No. 6:20-cv-06442-CJS. On information and belief, the accused product contained approximately 40 mg of zinc.

Defendants Engaged in Anticompetitive Conduct

52. A large number of the lawsuits settled very quickly after filing. As of November 2, 2021, on information and belief, eleven (11) of the lawsuits asserting the Abused Patents have

settled. On information and belief, this is due in part to the fact that the defendants could not afford to fight a protracted patent infringement case against a company the size of and with the resources of Bausch & Lomb. Some companies that settled appear to have removed AREDS-2 from their marketing and packaging. On information and belief, this was a result of the settlement. On information and belief, forcing competitors to cease using AREDS-2 in marketing was one goal of Bausch & Lomb in its recent spate of litigation. Companies selling products comprising, at least in part, the AREDS-2 formulation are entitled to use AREDS-2 in their marketing.

53. Bausch & Lomb's conduct in its litigation against ZeaVision has been abusive as well. For example, Bausch & Lomb filed suit against ZeaVision in the Western District of New York, a jurisdiction where venue was clearly and objectively improper under the patent venue statute and well-established Supreme Court precedent. When ZeaVision inquired as to the basis for venue in August 2020, the Defendants (through counsel) indicated that they believed ZeaVision might be willing to "waive" its venue objections, implicitly admitting that they knew venue was not proper in the Western District of New York.

54. Between August 2020 and the middle of January 2021, ZeaVision and the Defendants had numerous communications to explore the potential for finding an amicable solution to resolve their differences. Defendants made clear in their settlement negotiations with ZeaVision that they were not interested in monetary compensation for ZeaVision's alleged infringement of the Abused Patents. Counsel for Bausch & Lomb candidly admitted during negotiations that it wanted ZeaVision to cease using AREDS-2 in marketing. This was part of a pattern and practice of settlement negotiations on the Defendants' part that bordered on bad faith. The Parties were close to resolving the claims several times when Defendants would delay any

response and then move the proverbial goal posts by raising new legal issues or claims unrelated to the Abused Patents.

55. Defendants have no right to exclude ZeaVision from using AREDS and AREDS-2 in marketing. Defendants do not own any trademark rights in the acronyms AREDS or AREDS-2. In fact, any trademark rights to the AREDS or AREDS-2 marks (to the extent such rights exist) are owned by the Department of Health and Human Services—not the Defendants.

56. It has become clear that Defendants have chosen to use their vast resources to engage in an improper patent enforcement campaign against a group of much smaller entities in their own “backyard” in the Western District of New York, without regard to the patent venue statute and controlling authority from the Supreme Court, to make litigation more costly for ZeaVision, to improperly gain a perceived tactical advantage over these entities, and to improve Defendants’ posture in negotiations. Defendants’ specific decision to sue ZeaVision in the Western District of New York on the basis that ZeaVision might “waive” the venue requirement was unfounded, unreasonable, and indicative of Defendants’ improper use of patent litigation to coerce competitors. No reasonable patent litigant could believe that the WDNY Action against ZeaVision was properly venued in the Western District of New York. Defendants either failed to understand the unambiguous law of venue for patent cases, or they disregarded the unambiguous law for an improper purpose. Defendants’ unreasonable conduct in settlement negotiations further demonstrates that Defendants’ desire is not to enforce its patent rights under controlling law. Rather, Defendants’ goal is to monopolize the Relevant Market (defined *infra*).

57. In filing so many unfounded lawsuits for such an improper purpose, Bausch & Lomb abused government process. On information and belief, Bausch & Lomb engaged in its

actions in an attempt to stifle competition. Practically speaking, with a number of its competitors, Bausch & Lomb has succeeded.

58. Bausch & Lomb's conduct as described herein has suppressed, and will suppress, competition and produced anticompetitive effects in the Relevant Market, including causing ZeaVision antitrust injury and damages in the form of lost sales and lost market share proximately caused by Bausch & Lomb's unlawful and anticompetitive practices. In the event Bausch & Lomb is successful in its campaign, it will be able to control prices in the Relevant Market as it will be the only player.

59. There are high barriers to entry in the Relevant Market. Research and development of new products are expensive. Therefore, it is difficult for new competitors to enter the market.

60. It is believed that after a reasonable opportunity for discovery that it will be shown that Bausch & Lomb controls in excess of 80% of the relevant market.

61. Bausch & Lomb's antitrust violations as complained of herein are a material and substantial cause of ZeaVision's injuries. ZeaVision's injuries flowed from Bausch & Lomb's antitrust violations which caused competitive injury to ZeaVision. ZeaVision's injuries were a result of the anticompetitive consequences of Bausch & Lomb's antitrust violations. Bausch & Lomb's actions have also increased the costs of competing in the space, requiring ZeaVision to redesign its products and expend substantial legal fees in defense of Bausch & Lomb's baseless allegations.

62. ZeaVision's antitrust injuries include: (1) incurring legal fees in defending sham litigation; (2) being forced to modifying its packaging as a result of Bausch & Lomb's improper settlement tactics; (3) being forced to modify its already non-infringing formulation to be even further out of the specification of the Abused Patents as a result of Bausch & Lomb's improper

settlement tactics; and (4) being forced to divert resources and attention from research and production to fighting baseless litigation. If Bausch & Lomb is successful in its campaign to exclude competitors, Bausch & Lomb will eliminate all other competition in the market and become the only game in town.

63. The challenged conduct affected the prices, quantity, or quality of goods or services. Bausch & Lomb has both monopoly and market power.

64. ZeaVision's injuries were of a type the antitrust laws were intended to prevent.

65. At least one other competitor of Defendants, Pharmavite, LLC, has filed suit seeking to hold Defendants accountable for their monopolistic acts.

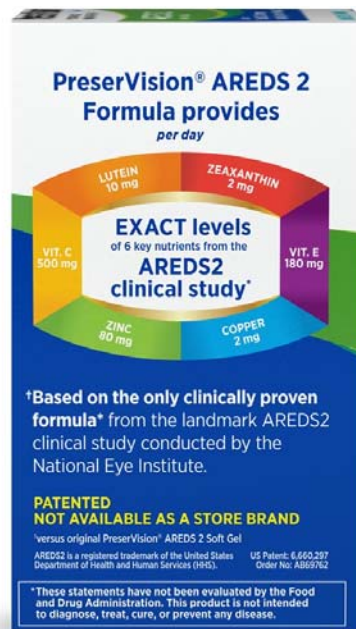
66. Bausch & Lomb is using its Abused Patents to reduce and restrict output in the Relevant Market by forcing competitors to cease using AREDS-2 in their advertising. If Bausch & Lomb is successful in excluding all of its competitors from using AREDS-2, then consumers will believe that Bausch & Lomb is the only company selling products meeting the AREDS-2 standard.

Bausch & Lomb's Misleading Marketing

67. As if Bausch & Lomb's abuse of its patents was not enough to give it an improper competitive edge, it has also misled consumers regarding the patent protection applicable to its products as well as their efficacy for treating diseases.

68. Bausch & Lomb falsely claims that its AREDS-2 formula PreserVision® products are protected by patents and are the only patented products covering AREDS-2. On information and belief, this is in further attempt to monopolize, maintain its monopoly in, or attempt to monopolize the Relevant Market (defined *infra*). However, the composition patent expired in

March 2021. As shown below, as of December 13, 2021, Bausch & Lomb is still falsely claiming on its website that its PreserVision® AREDS-2 formula is patented.s



69. In addition, Bausch & Lomb claims on its website that “This patented formula is not available as a store brand.” See <https://www.preservision.com/Products/Choose-Your-PreserVision/areds-2-formula-miniGels/>, (last accessed 3/1/2022).

70. Bausch & Lomb’s claims that its AREDS-2 products are patented is false. The ‘297 Patent was, on information and belief, the only patent owned by Bausch & Lomb that allegedly covered the composition of Bausch & Lomb’s AREDS-2 products. Even if the ‘297 Patent were valid during its enforceable term, after March 23, 2021, any direct or indirect claim by Bausch & Lomb that the AREDS-2 formula remains patented is literally false. Nor, after March 23, 2021, could Bausch & Lomb properly seek to prevent competing sales of the AREDS-2 formula in the United States for any use. Accordingly, Bausch & Lomb’s post-March 23, 2021 label claim that its product is “patented” is incorrect and falsely conveyed to consumers, in furtherance of Bausch & Lomb’s monopolization, attempted monopolization, and maintenance and attempted

maintenance of its monopoly of the Relevant Market, that the AREDS-2 Formula used in PreserVision® is unique to that product, is different from competing AREDS-2 Formula supplements, is superior to competing AREDS-2 Formula supplements, including ZeaVision's products, and that, because of the '297 Patent, no other dietary supplement can use the AREDS-2 Formula.

71. To the extent Bausch & Lomb's claims of patent coverage on its label or in its advertising refer to the '522 Patent, such claims would also be false at least because the '522 Patent cannot cover the AREDS-2 formula as a matter of law because it is a method-of-use patent. Moreover, Bausch & Lomb cannot lawfully practice or direct other persons to practice the claimed methods of use, all of which require the treatment of a disease, without the required approvals from the FDA (which on information and belief, Bausch & Lomb does not have). Bausch & Lomb's conduct (i.e., its claims of patent coverage on its label or in its advertising) are in furtherance of Bausch & Lomb's monopolization, attempted monopolization, and maintenance and attempted maintenance of its monopoly of the Relevant Market.

72. Even after the '297 Patent expired, and with knowledge that it had expired, Bausch & Lomb persisted in making reference to PreserVision®'s "patented formula" through ubiquitous statements not only on bottles of the product sold but also on Bausch & Lomb's websites and websites for e-tailers such as Amazon, creating, on information and belief, consumer misperception and illegally anticompetitive competition for ZeaVision's supplements, resulting in competitive injury to ZeaVision—all of which Bausch & Lomb did and continues to do in its monopolization and attempted monopolization of the Relevant Market.

73. The claim that Bausch & Lomb has the "only" patented AREDS-2 compliant supplement is also literally false. ZeaVision owns a number of patents protecting its AREDS

supplements, including several which Bausch & Lomb's products infringe. Given that the claim is literally false, it must have been made in bad faith.

74. Because Bausch & Lomb's claims of patent protection are false, they have a tendency to deceive the audience. Bausch & Lomb has made these statements in interstate commerce. On information and belief, these statements were made in bad faith as they are false and, on information and belief, Bausch & Lomb knows they are false.

75. Bausch & Lomb's claim that it sells the "only" patented AREDS-2 supplement is, on information and belief, an attempt to convince customers that its products are superior to those of its competitors. This restraint of trade was a material deception. This was in an effort to promote the sales of its own products over those of its competitors and potentially to block the entry of new competitors into the market, all in restraint of trade.

The Relevant Market for AREDS and AREDS-2 Oral Age-Related Macular Degeneration Vitamin Supplements

76. On information and belief, Bausch & Lomb is by far the largest participant in the Relevant Market for AREDS and AREDS-2 Oral Age-Related Macular Degeneration Vitamin Supplements (the "Relevant Market"). On information and belief, Bausch & Lomb sold well more than \$200 million worth of PreserVision® products in 2020—3% of its total revenue. On information and belief, Bausch & Lomb expects products sold under the PreserVision® brand to be a key driver for growth of its global vision care, surgical, consumer and ophthalmic Rx businesses.

77. PreserVision® and Ocuvite® are responsible for approximately 10% of Bausch & Lomb's revenue derived from their segment. On information and belief, those products became more important for Bausch & Lomb during the COVID-19 pandemic as the postponement of

certain surgical and elective medical procedures as well as the decrease in consumption of contact lenses impacted sales volumes.

78. Because oral supplements based on the AREDS and AREDS-2 tests are based on a set standard, all products in that segment are identical to or substantially compete with each other. The products serve the same function—namely compliance with a formula clinically correlated with the prevention or slowing of AMD. Bausch & Lomb has admitted the substitutability of the products by filing lawsuits, although baseless, for infringement based on the Abused Patents which it claims cover its PreserVision® products.

79. Use of AREDS and AREDS-2 is an essential part of marketing for companies in the Relevant Market. The NIH owns the trademarks for AREDS and AREDS-2. The NIH describes vitamins containing the ingredients found by the studies to reduce AMD as “AREDS vitamins” and “AREDS-2 Supplements.” *See* National Institute of Health, *AREDS/AREDS-2 Frequently Asked Questions*, <https://www.nei.nih.gov/research/clinical-trials/age-related-eye-disease-studies-aredsAREDS-2/aredsAREDS-2-frequently-asked-questions> (last accessed Dec. 1, 2021). Bausch & Lomb even advises people to “[t]alk to your doctor to determine if the AREDS-2 formula is right for you.” Bausch & Lomb, *The AREDS Story*, <https://www.preservision.com/Why-PreserVision/The-AREDS-Story/> (last accessed Dec. 1, 2021).

80. The use of AREDS in marketing to distinguish AREDS supplements from non-AREDS supplements is critical. Bausch & Lomb even emphasizes the difference between AREDS vitamins and normal multivitamins in its advertising. Bausch & Lomb also makes clear that normal multivitamins are not a substitute for AREDS vitamins. For example, a website maintained, on information and belief, by Bausch & Lomb, states:

You might be wondering why you can't just eat lots of spinach or take a multivitamin—after all, most multivitamins, contain the same nutrients as the AREDS-2 formula—and more. The answer is no.

AREDS vitamins

The AREDS-2 formula contains much higher doses of certain vitamins and minerals than diet or multivitamins alone, in a carefully balanced combination.

<https://www.sightmatters.com/article-detail-topics/vitamins-for-macular-degeneration/> (last accessed Dec. 1, 2021).

81. Other than AREDS supplements, there are no good treatment options for addressing the onset of AMD symptoms.

82. The effect of Bausch & Lomb's patent infringement lawsuit spree has been to stop competitors from advertising (truthfully) that they are in compliance with AREDS or AREDS-2. On information and belief, this was Bausch & Lomb's intent in filing all of the infringement lawsuits—to force competitors to stop using AREDS in their marketing so that Bausch & Lomb is

the only game in town. It is believed that after a reasonable opportunity for discovery, evidence will demonstrate that Bausch & Lomb's motivation in filing the patent infringement lawsuits was to dominate the Relevant Market. When consumers are told by their doctors to purchase AREDS vitamins, if Bausch & Lomb succeeds in its goal, Bausch & Lomb's products will be the only ones that appear available. This is in spite of the fact that Bausch & Lomb's formula is in fact *less* safe for consumers than its competitors' formulas, as discussed above. As such, in addition to freezing competitors out of the Relevant Market, Bausch & Lomb's conduct directly harms the health of consumers.

83. If Bausch & Lomb is successful in excluding its competitors from advertising using AREDS, this will give Bausch & Lomb monopolistic control over the Relevant Market. Consumers will have no way of knowing that there are competing products and, if their doctor recommends use of an AREDS supplement, will only believe they have one option: Bausch & Lomb's products. Because Bausch & Lomb has already settled, on information and belief, eleven (11) of the patent infringement cases, it is likely to succeed in becoming a monopoly if it is not stopped.

84. Bausch & Lomb has demonstrated by its actions that it believes it controls 100% of the AREDS-2 supplement market because of the Abused Patents. However, as discussed above, the true sweep of the Abused Patents is not so broad.

85. The geographic area for the Relevant Market is the United States of America. Both Parties sell their products to consumers nationwide, including over the internet.

CLAIMS

COUNT I: (Violation of the Lanham Act)

86. ZeaVision incorporates all preceding paragraphs as though fully set forth herein.

87. Bausch & Lomb intentionally, knowingly, and/or recklessly published false and/or misleading statements in commercial advertising or promotion. Bausch & Lomb's actions actually deceived or had the capacity to deceive a substantial segment of the target audience. Bausch & Lomb's false or misleading statements were and are material to the decisions customers make in deciding to purchase Bausch & Lomb's goods and were made for the purpose and/or had the effect of causing customers to utilize products offered by Bausch & Lomb.

88. In so doing, Bausch & Lomb violated the Lanham Act, 15 U.S.C. § 1125(a)(1)(B). As a result of Bausch & Lomb's actions, ZeaVision suffered damages in an amount to be determined at trial.

**COUNT II:
(Violation of the Sherman Act § 2)**

89. ZeaVision incorporates all preceding paragraphs as though fully set forth herein.

90. Bausch & Lomb has acted as set forth above with the specific intent to monopolize the Relevant Market.

91. In addition, Bausch & Lomb engaged in monopolistic and anticompetitive conduct by at least the following:

- a. engaging in patent misuse;
- b. threatening and filing baseless litigation;
- c. filing sham petitions;
- d. deceiving consumers;
- e. falsely claiming patent protection;
- f. making false statements that it sells the only patented AREDS-2 supplement;
- g. forcing and attempting to force competitors to cease using AREDS and AREDS-2 in their marketing; and

- h. requiring, on information and belief, cessation of use of AREDS and AREDS-2 in marketing by companies actually implementing those formulas as part of settlement agreements.

92. There is a dangerous probability that Bausch & Lomb will achieve monopoly power or already has monopoly power. Bausch & Lomb controls a large percentage share of that Market and any success that Bausch & Lomb has in excluding ZeaVision and other competitors from the Relevant Market will confer a monopoly on Bausch & Lomb. In addition, Bausch & Lomb has already had success in forcing other competitors to cease using AREDS-2 in their marketing. ZeaVision has sustained antitrust injury.

93. Through Bausch & Lomb's conduct described herein and other conduct likely to be revealed in discovery, Bausch & Lomb has willfully and unlawfully maintained and enhanced its monopoly power. At all relevant times, Bausch & Lomb possessed and currently exercises monopoly power in the Relevant Market, as described herein.

94. Bausch & Lomb's conduct as described herein constitutes exclusionary conduct within the meaning of Section 2 of the Sherman Act.

95. Bausch & Lomb's conduct as described herein has suppressed, and will suppress, competition and produced anticompetitive effects in the relevant markets, including causing ZeaVision antitrust injury and damages as set forth herein proximately caused by Bausch & Lomb's unlawful and anticompetitive practices.

96. Bausch & Lomb's conduct has no procompetitive benefit or justification. The anticompetitive effects of Bausch & Lomb's behavior outweigh any purported procompetitive justifications.

97. By its conduct, Bausch & Lomb has violated Section 2 of the Sherman Act (15 U.S.C. § 2), thereby entitling ZeaVision to relief.

PRAYERS FOR RELIEF

WHEREFORE, Plaintiff ZeaVision, LLC, prays that this Court:

1. Enter judgment against Bausch & Lomb on Counts I through II of this Complaint;
2. Enter an Order enjoining Defendant from filing frivolous lawsuits and forcing competitors to cease using AREDS in marketing;
3. Award ZeaVision its damages on Counts I through II in an amount to be determined at trial and trebled as allowed by statute;
4. Award prejudgment interest to ZeaVision;
5. Award ZeaVision its attorneys' fees, costs, and post-judgment interest; and
6. Grant such other and further relief as this Court deems just and proper.

Dated: March 4, 2022

Respectfully submitted,

/s/ Anthony G. Simon

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and accurate copy of the foregoing document was served upon all counsel of record via the Court's CM/ECF on March 4, 2022.

/s/ Anthony G. Simon